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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,018	09/11/2002	Elazar Sonnenschein	A34907PCTUSA;066031.0168	5861
21003	7590	07/27/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 07/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/030,018

Applicant(s)

SONNENSCHEN ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 31, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/03/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites "one of said anvil portions" in lines 3-4, when previously reciting only "an anvil portion" in lines 2-3. This renders the claim unclear. Note that there is no prior art rejection of claims 2-12 and 35.
2. Claim 31 recites the limitation "the pinholes" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 15, 16-21, 25, 26, and 36-41 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,338,737 B1 to Toledano. Regarding Claim 1, Toledano discloses a stapling device for endoscopic use with a flexible portion (21) [Column 8, lines 30-37] located between a staple firing portion (11) and an anvil

portion (18) [see Figures 2 and 4A]. The staple firing portion and anvil are longitudinally displaced from each other, meaning that the staple firing portion is located distally to the anvil [the well-known configuration of such a stapler is described in Column 1, lines 40-63].

4. Regarding Claim 15, Toledano discloses a stapler having an anvil (18) located proximate to the distal end of the flexible portion (21) and a staple firing portion (11) located on (attached to) the flexible portion (21).
5. Regarding Claim 16, both the staple firing portion (11) and the anvil (18) are located on (attached to/touching) the flexible portion (21).
6. Regarding Claims 17-20, the flexible portion has an articulation section at its distal end, connected to the more rigid (although *still somewhat flexible* so as to be able to maneuver through the intestines) section (83) [Column 8, lines 34-38]. The flexible portion (21) has an *infinite number* of places where it can be articulated or bent. For example, when the head is in its extended position (as shown in Fig. 1c) and the flexible portion (21) is bent/articulated as it is in Fig. 1c, and then the flexible portion is pulled taut, the staple firing portion (11) will be brought into a correct working (abutting) relationship with the anvil (18).
7. Regarding Claim 21, Toledano discloses a stiff, non-circular pin located close to the staple firing portion that fits inside of a hole having a corresponding shape to align the staple firing mechanism with the anvil and make sure that they are in correct working relationship [Column 7, lines 25-32].

8. Regarding Claim 25, Toledano discloses a staple firing portion with a cartridge of staples [Column 7, lines 38-45]. A cartridge contains many staples *in some orderly arrangement*, which is the definition of an array.
9. Regarding Claim 26, Toledano's staple pushers are pins, which push the staples and are activated by the user outside of the body (thus they are located proximal to the stapling mechanism) [Column 7, lines 38-45].
10. Regarding Claims 36-41, Toledano explains that his system should be used with an endoscope [Column 3, lines 41-45] and all of the commonly associated accoutrements, such as air/water supply [Column 9, lines 35-50], video [Column 10, lines 19-21], and light [Fig. 8].
11. Claims 1, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,159,146 to El Gazayerli. Regarding Claim 1, El Gazayerli discloses an endoscopic stapler having a flexible portion (28) between the distal anvil (24) and a proximal staple firing mechanism (20) [Column 3, lines 55-65; Fig-2B].
12. Regarding Claims 13 and 14, the staple firing portion (20) is located proximally to the proximal end of the flexible portion and the anvil portion is located on the distal tip of the flexible portion [Fig-2B].

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 6,338,737 B1 to Toledano in view of U.S. Patent No. 6,716,233 B1 to

Whitman. Toledano discloses all of the elements of claim 1, as explained above.

However, Toledano does not disclose using magnetics or ultrasound to assist the

stapling mechanism and anvil in coming together. However, Whitman discloses a

similar stapling mechanism and teaches that magnetics/ultrasound should be used in

the staple driving and anvil mechanisms in order to bring them together the exact

proper distance so as to staple the tissue precisely [Column 4, lines 32-42]. The

magnetics (and other sensors) allow the procedure to be done using remote controls

[Column 4, lines 62-66]. Column 5, lines 26-45 explain that the user can steer the

anvil relative to the staple driver using a joystick or similar mechanism. This passage

also makes it clear that the way the user knows how to position the one relative to the

other is *because of the electrical sensing apparatus* (magnet/LED/etc...).

14. Regarding Claims 21-24, specifically Whitman's Figure 4 explains that

magnetics/ultrasound helps the user position the anvil with regards to the staple firing

mechanism. Column 5, lines 46-60 explain that ultrasound and other communication

means may be used. If the control unit communicates with the driver unit

components (anvil and stapler) using magnetics, then each of the anvil and stapler

must have transducers and receivers. Light emitting elements (154) are located on the

anvil and light sensors (152) are located on the staple firing mechanism [Column 10,

lines 15-22].

15. Claims 27, 28, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,338,737 B1 to Toledano in view of U.S. Patent No. 4,612,933 to Brinkerhoff et al. Toledano discloses a stapler having a cartridge, but is not specific about the details of his cartridge. However, Brinkerhoff discloses a staple cartridge that is indexable [Column 3, lines 24-27] and that has windows [Fig. 22]. Figure 22 shows the cartridge having several holes at the top of the cartridge. These holes could be called windows. Brinkerhoff's staple cartridge has the advantage of being able to hold more than one load of staples so as to be able to be actuated several times (applying several rounds of staples) before needing to be refilled [Column 1, lines 6-12]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a staple cartridge of similar design to Brinkerhoff's rather than the staple cartridge of Toledano in order to be able to staple many times without stopping to reload, as taught by Brinkerhoff.
16. Regarding Claim 28, the windows/holes in Brinkerhoff's cartridge could be said to assist in stapling because they are apparently a necessary part of the stapling cartridge.
17. Regarding Claim 30, each array has at least five staples [Fig. 32].
18. Regarding claims 32 and 33, the modified Toledano discloses the invention except for having the specified number of windows/holes. However, it would have been an obvious matter of design choice to one of ordinary skill in the art to have six or four windows, as it has been held that duplicating parts or adding an identical part involves only routine skill in the art.

19. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,338,737 B1 to Toledano in view of U.S. Patent No. 4,612,933 to Brinkerhoff et al, in further view of U.S. Patent No. 4,848,637 to Pruitt. The modified Brinkerhoff stapler has only two rows. However Pruitt discloses having three rows of staples (or four) instead of only two. Pruitt's rows each have five staples [Fig. 12]. Pruitt explains that when more than two rows of staples were needed previously one had to use multiple staplers [Column 2 line 66- Column 3 line 15]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a cartridge to apply three rows of staples as taught by Pruitt instead of the mere two disclosed by Brinkerhoff in order to more efficiently (and rapidly) apply a large number of staples at once.

20. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,159,146 to El Gazayerli in view of Publication No. US 2001/0054636 A1 to Nicolo. El Gazayerli discloses a stapler according to claim 1, but fails to disclose a safety means preventing stapling when the two separate elements are not aligned. However, Nicolo discloses {in paragraph [008]} a means a safety mechanism that prevents stapling when the anvil and stapler are unaligned. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to include a safety mechanism as taught by Nicolo in El Gazayerli's stapler in order to prevent the dangerous or premature firing of the stapler within the human body.



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*Response to Arguments*

21. Applicant's arguments, see Response to Election/Restriction Requirement, filed 05/10/2004, with respect to the requirement for the election of species have been fully considered and are persuasive. The requirement for election of species has been withdrawn and all of the claims (1-41) have been examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BCP*  
BCP  
July 23, 2004

*Julian W. Woo*

JULIAN W. WOO  
PRIMARY EXAMINER